K000053

MAR 15 2000

Section 3
ACL 9000 System - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
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Summary Prepared:

January 6, 2000

Name of the Device:

ACL 9000 System

Classification Name(s):

81GKP	Instrument, Coagulation, Automated	
864.5400	Coagulation Instrument	Class II
81JPA	System, Multipurpose for In Vitro Coagulation Studies	
81GGN	Plasma, Coagulation Control	
864.5425	Multipurpose system for In Vitro Coagulation Studies	Class II
81JBQ	Antithrombin III Quantitation	
864.7060	Antithrombin III Assay	Class II
81GGP	Test, Qualitative and Quantitative Factor Deficiency	
864.7290	Factor Deficiency Tests	Class II
81DAP	Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control	
864.7320	Fibrinogen/Fibrin Degradation Products Assay	Class II
81GIS	Test, Fibrinogen	
81GIL	Plasma, Fibrinogen Control	
864.7340	Fibrinogen Determination System	Class II
81KFF	Assay, Heparin	
864.7525	Heparin Assay	Class II
81GJS	Test, Time, Prothrombin	
864.7750	Prothrombin Time Test	Class II
81GJA	Test, Thrombin Time	
864.7875	Thrombin Time Test	Class II
81GFO	Activated Partial Thromboplastin	
864.7925	Partial Thromboplastin Time Tests	Class II

Identification of Predicate Device(s):

ACL 6000 System (Predicate Device)	K961991

Reagents used in performance testing were cleared as follows:

Assess High Abnormal Control	K931118
Assess Low Abnormal Control	K931117
Abnormal Chromogenic Control Plasma Level 1/2	K864271
Antithrombin	K980499
APC Resistance V	K963111
APTT-SP	K973306
D-Dimer	K972696
Fibrinogen-C	K931721
Heparin	K980242
Plasmin Inhibitor	K981696
Plasminogen	K981200
ProClot	K912711
Protein C	K980875
Protein S	K930327
PT-Fibrinogen	K862301
PT-Fibrinogen HS	K923921
PT-Fibrinogen HS Plus	K933252
Thrombin Time	K862301

NOTE: The other reagents used (IL Test Factor Deficiency assays, APTT-C, Low and High Heparin Controls, Low Fibrinogen Control, Assess Normal Control and Assess Calibration Plasma) were submitted as part of the ACL instrument 510(k)s, most recently with the predicate device: ACL 6000 System (K961991).

Description of the Device/Intended Use(s):

The ACL 9000 System is a fully automated, high-productivity analyzer designed specifically for *in vitro* diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The system provides results for both direct hemostasis measurements and calculated parameters.

The ACL 9000 System is an upgraded version of the existing ACL 6000 System (K961991) with additional hardware and software features. The same reagents and quality control materials associated with the ACL 6000 System (and the entire ACL Hundred/Thousand Series family members) are intended for use with the ACL 9000 System with no changes to their formulations or performance characteristics.

The new software/hardware features include an integrated rotor exchanger module, optional decapper module, improved user interface and new automated photometric station cover. There is no impact on how the system measures clotting times or performs chromogenic assays.

The intended use, methodology, working range and analytical results of the ACL 9000 System are substantially equivalent to those of the predicate device: ACL 6000 System.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The ACL 9000 is substantially equivalent in performance, intended use, safety and effectiveness to the ACL 6000 System (predicate device) for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis.

Summary of in-house performance data:

Within Run Precision

Within run precision assessed over multiple runs (10) using multiple levels of control plasma gave the following results:

Reagent	Control Level	n	Mean	%CV
Antithrombin (%)	Normal	30	112.3	2.33
	Abnormal 1	30	58.3	3.23
	Abnormal 2	30	25.7	3.42
APC Resistance V (Normalized Ratio)	Level 1	40	0.98	1.82
	Level 2	40	0.62	1.96
APTT-SP (Seconds)	Normal	60	29.3	1.27
	Abnormal 1	60	49.2	0.98
	Abnormal 2	60	61.3	1.72
D-Dimer (ng/mL)	Level 1	90	263	6.54
	Level 2	90	673	3.00
Factor VII (%) with PT-Fibrinogen	Normal	40	78.9	3.32
	Abnormal 1	40	55.7	3.01
	Abnormal 2	40	24.4	4.04
Factor VIII (%) with APTT-SP	Normal	40	77.0	8.39
	Abnormal 1	40	84.0	6.67
	Abnormal 2	40	39.2	6.67
Fibrinogen-C (mg/dL)	Normal	80	269.3	3.20
	Low Fibrinogen	80	97.2	2.09
Heparin (U/mL)	0.85 LMW Heparin	30	0.8	2.02
	Low Heparin	30	0.3	4.33
	High Heparin	30	0.7	2.65
Plasmin Inhibitor (%)	Normal	50	110.0	1.21
	Abnormal 1	50	68.4	2.52
	Abnormal 2	50	35.3	3.82
Plasminogen (%)	Normal	50	106.2	2.78
	Abnormal 1	50	69.2	2.94
	Abnormal 2	50	31.3	3.31
ProClot (%) with APTT-SP	Normal	80	83.0	3.71
	Abnormal 1	80	48.6	5.12
Protein C (%)	Normal	40	95.4	1.68
	Abnormal 1	40	51.1	1.77
	Abnormal 2	40	22.8	3.31
Protein S (%)	Normal	70	103.1	2.60
	Abnormal 2	70	50.7	4.36
PT (Seconds)	Normal	60	12.8	1.30
	Abnormal 1	60	19.2	1.75
	Abnormal 2	60	29.1	2.07
PT-Based Fibrinogen (mg/dL)	Normal	90	243.0	7.06
	Low Fibrinogen	90	106.4	7.14
Thrombin Time-8 mL (Seconds)	Normal	90	17.9	3.39
	Heparin Sample	90	22.8	3.57

Summary of in-house performance data (Cont.):

Method Comparison

In method comparison studies evaluating citrated plasma samples, the ACL 9000 and the ACL: 6000 (predicate device) were shown to be statistically similar for the tests listed below.

Reagent	n	Slope	Intercept	r	Sample Range
Antithrombin (%)	48	1.08	-3.031	0.995	14-125
APC Resistance V (Normalized Ratio)	57	0.97	0.021	0.993	0.457-1.105
APTT-SP (Seconds)	54	1.04	-1.471	0.998	27.5-96.2
D-Dimer (ng/mL)	46	0.91	86.596	0.996	56-1083
Factor VII (%) with PT-Fibrinogen	48	1.02	-2.605	0.996	2.4-170
Factor VIII (%) with APTT-SP	47	0.96	0.6184	0.990	0.96-199.2
Fibrinogen-C (mg/dL)	54	1.10	-14.032	0.998	74-766
Heparin (U/mL)	50	1.03	-0.002	0.996	0.00-1.21
Plasmin Inhibitor (%)	57	0.91	8.642	0.990	49.6-125.0
Plasminogen (%)	57	0.99	3.525	0.989	18.4-150.8
ProClot (%) with APTT-SP	54	0.98	1.912	0.995	10.7-199.1
Protein C (%)	52	1.10	-5.781	0.998	22-317
Protein S (%)	54	0.92	2.935	0.993	12-117
PT (Seconds)	52	1.07	-0.838	0.999	10.4-25.1
PT-Based Fibrinogen (mg/dL)	51	0.93	35.038	0.990	49.7-844.7
Thrombin Time–8 mL (Seconds)	54	1.01	1.010	0.998	15.5-43.5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2000

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K000053
Trade Name: ACL 9000 System
Regulatory Class: II
Product Code: JPA
Dated: January 6, 2000
Received: January 7, 2000

Dear Ms. Marble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K000053

Device Name: ACL 9000 System

Indications for Use:

The ACL 9000 System is a fully automated, high-productivity analyzer designed specifically for *in vitro* diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The system provides results for both direct hemostasis measurements and calculated parameters.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Walker

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000053

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)